

### **REMARKS**

Claim 8 has been amended as suggested by the Examiner to address the objection posed in the Office Action dated April 21, 2009. Applicants submit that no new matter was added.

The Office Action rejects claim 5 under 35 USC 112, second paragraph, as indefinite. Applicants respectfully traverse. As is known in the art and identified in the attached Declaration, a unit of umbilical cord blood (UCB) means an amount of UCB obtained from 1 woman after parturition. This size of a unit can vary but persons skilled in the art would recognize there is a maximum. All that is required by claim 5 is a minimum amount. Accordingly, the Applicants submitted that the metes and bounds of the claim are defined. Withdrawal of the rejection is respectfully requested.

Applicants thank the Examiner for the courtesy of an interview on July 16, 2009, during which claims 1-8 were discussed in light of Erices *et al.* and Nishikawa *et al.* references. As discussed, submitted herewith is a Declaration under 37 CFR 1.132 detailing the differences of the present invention over the cited references. The specifics of this Declaration are discussed as related to the rejections.

### **Rejections under 35 USC 103**

The Office Action rejects claims 1-4, 6, and 7 over Erices *et al.* (British Journal of Haematology 2000, 109: 235-242), in view of Nishikawa *et al.* (publ. no. US 2004/0235160), and claims 1, 5, and 8 in view of these references and Goodwin *et al.* (Biology of Blood and Marrow Transplantation 2001, 7: 581-588). Applicants respectfully traverse by filing the attached Declaration and presenting the following arguments.

As acknowledged in the Office Action (page 6), Erices *et al.* disclose a method of isolating mononuclear cells but do not disclose culturing conditions to isolate mesenchymal stem cells (MSCs). As set forth in the Declaration, conventional methods

use a different method than utilized in the present application (see Declaration, paragraph 4). Whereas the isolation of MSCs from bone marrow is not difficult using methods such as Erices *et al.*, isolation of MSCs from UCB is very challenging. Thus, before the present invention, UCB was used to isolate hematopoietic stem cells (HSCs) rather than MSCs. Nishikawa *et al.* does not teach isolation of MSCs at all but only growth of HSCs. In contrast, the growth medium detailed in Example 3 and in Table 2 of the present application provide the culturing media specifics, which "unexpectedly proves a 49 fold increase in the isolation of MSCs from UCB" (Declaration, paragraph 7). Compared to the conventional methods as exemplified by Erices *et al.* and Goodwin *et al.*, which results in a 2% success rate of 1 unit of MSCs out of 50 units, the present method that is detailed in Example 3 of the present application results in a 98% success rate (49 units of MSCs out of 50 units). This result is unpredictable in view of the media used by Nishikawa *et al.* to grow HSCs.

During the interview, the Examiner indicated that paragraph 0076 of Nishikawa *et al.* was being interpreted to include culturing of MSCs as well as HSCs. However, careful reading of paragraph 0076 and Example 5 of Nishikawa *et al.* in view of paragraph 8 of the Declaration indicates that the MSCs were only used as feeder cells for growing HSCs, and also that Nishikawa *et al.* do not grow MSCs. Further, Nishikawa *et al.* only grow CD34-positive HSC cells and they do not disclose culturing MSCs.

Accordingly, the combination of Erices *et al.* and Nishikawa *et al.* fails to render the present invention obvious and the rejection should be withdrawn.

#### **Obviousness-type double patenting**

The Office Action indicated a provisional obviousness-type double patenting rejection over claims of the Applicants' US patent application no. 10/579,071. Applicants will submit a terminal disclaimer on the indication of allowable claims in the presently pending application.

**CONCLUSIONS**

Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. Accordingly, Applicants request that the Examiner issue a Notice of Allowance for pending claims 1-8 and that the application be passed to issue. Applicants respectfully request that a Notice of Allowance of pending claims 1-8 be timely issued in this case.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided. The Commissioner is authorized to charge any deficiency in any patent application processing fees pursuant to 37 CFR §1.17, including extension of time fees pursuant to 37 CFR §1.17(a)-(d), associated with this communication and to credit any excess payment to Deposit Account No. 22-0261, under Order No. 36470-231114.

Respectfully submitted,

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